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WASHINGTON, D.C. 20460

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HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

October 15, 1999

MEMORANDUM

SUBJECT: ***PYRIDATE*** - Report of the FQPA Safety Factor Committee

FROM: Brenda Tarplee, Executive Secretary
FQPA Safety Factor Committee
Health Effects Division (7509C)

THROUGH: Ed Zager, Chairman
FQPA Safety Factor Committee
Health Effects Division (7509C)

TO: Melba Morrow, Branch Senior Scientist
Registration Action Branch 1
Health Effects Division (7509C)

PC Code: 128834

The FQPA Safety Factor Committee met on October 4, 1999 to evaluate the hazard and exposure data for pyridate and recommended that the FQPA Safety Factor (as required by Food Quality Protection Act of August 3, 1996) be removed (1x) in assessing the risk posed by this chemical.

I. HAZARD ASSESSMENT

(*Correspondence:* M. Morrow to B. Tarplee dated September 22, 1999)

A. Adequacy of the Toxicology Database

The toxicology database for pyridate is complete and there are no data gaps. On November 3, 1997, the HIARC concluded that a developmental neurotoxicity study was not required.

However, the FQPA SFC recommended that a developmental neurotoxicity study should be required since pyridate is a known neurotoxicant which produces clinical signs and cholinesterase depression in adult animals.

B. Determination of Susceptibility

The toxicity data provided no indication of increased susceptibility for rats or rabbits to *in utero* and/or postnatal exposure to pyridate. In the prenatal developmental toxicity studies in rats and rabbits and the 2-generation reproduction study in rats, effects in the offspring were observed only at or above treatment levels which resulted in evidence of parental toxicity. Additionally, these effects were not considered to be qualitatively more serious than the effects observed in the parents.

II. EXPOSURE ASSESSMENTS

A. Dietary (Food) Exposure Considerations

(*Correspondence:* M. Morrow to B. Tarplee dated September 22, 1999)

Tolerances are established for combined residues of the herbicide pyridate, its metabolite, 6-chloro-3-phenyl-pyridazine-4-ol (CL-9673) and conjugates of the metabolite, all expressed as pyridate in or on cabbage, corn, peanuts, and garbanzo beans at levels ranging from 0.03 - 0.1 ppm (40 CFR 180.462). Tolerances are now proposed for the use of pyridate on mint, brassica, and collards. There are no established Codex MRLs for pyridate.

The HED Dietary Exposure Evaluation Model (DEEM) will be used to assess the risk from acute and chronic dietary exposure to pyridate residues in food. At the time of this meeting, these analyses were not complete. Since there are no monitoring data or percent crop treated (%CT) information, it is expected that these analyses will be unrefined (Tier 1) resulting in an overestimate of the dietary (food) exposure resulting from the use of pyridate.

B. Dietary (Drinking Water) Exposure Considerations

(*Correspondence:* S. Dutta to B. Tarplee dated September 29, 1999)

The environmental fate database for pyridate is adequate for the characterization of drinking water exposure. The data indicate that pyridate is rapidly hydrolyzed to its primary degradate, CL-9673, and that both of these compounds will be short lived in the environment when exposed to sunlight.

No monitoring data are available for pyridate. Estimated Environmental Concentrations (EECs) have been calculated for ground and surface water based on the current EFED first level screening models, SCI-GROW and GENEEC respectively :

> The GENEEC model was used to estimate surface water concentrations for pyridate using the garbanzo beans (chick peas) application scenario. The modeling results indicate that pyridate has the potential to move into surface waters, especially during times of unusually heavy rainfall.
>
> The SCI-GROW model was used to estimate ground water concentrations due to possible leaching following pyridate application to mint.

C. Non-Occupational (Residential) Exposure Considerations

(*Correspondence:* M. Morrow to B. Tarplee dated September 22, 1999)

Non-occupational exposure resulting from the use of pyridate is not expected.

III. SAFETY FACTOR RECOMMENDATION AND RATIONALE

A. Recommendation of the Factor

The Committee recommended that the FQPA safety factor for protection of infants and children (as required by FQPA) be **removed (1x).**

B. Rationale for Removing the FQPA Safety Factor

The Committee concluded that the safety factor could be removed because:

1. The toxicology database is complete for the assessment of the effects following *in utero* and/or postnatal exposure to pyridate;

2. The toxicity data provided no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure;

3. the requirement of a developmental neurotoxicity study is not based on the criteria reflecting some special concern which are generally used for requiring a DNT study and an FQPA safety factor (e.g.: neuropathy in adult animals; CNS malformations following prenatal exposure; brain weight or sexual maturation changes in offspring; and/or functional changes in offspring)[1] and therefore does not warrant an FQPA safety factor; and

4. The exposure assessments will not underestimate the potential dietary and non-dietary exposures for infants and children from the use of pyridate.

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[1]This is an interim step towards accordance with the proposed 'OPP POLICY ON DETERMINATION OF THE APPROPRIATE FQPA SAFETY FACTOR(S) FOR USE IN THE TOLERANCE-SETTING PROCESS' which was presented to the FIFRA SAP meeting in May, 1999 and placed in the Docket for Public Comment (64FR37001; 7/8/99; Docket No. 37001).

FQPA SAFETY FACTOR COMMITTEE MEETING

40CT1999

PYRIDATE

Name	Division/Branch
[signature]	HED
Rick Keigwin	RD
[signature]	EFED
Debbie McCall	RD
[signature]	RAB 1
George Kramer	RAB1
SUBJOY DUTTA	EFED/ERB2
Kathy Monk	SRRD
[signature]	HED/RAB4
[signature] Fleuchaus	OGC
[signature]	HED/ERB4
[signature]	HED/SAB
Brenda Tarplee	HED/SAB

Note: E. Zager not present (attending another meeting)
B. Burnam presiding.